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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/830,034	04/23/2004	Thomas J. Wood	IMED-0009-US	7516
40575	7590	06/14/2007	EXAMINER	
OLDS, MAIER & RICHARDSON 1000 DUKE STREET ALEXANDRIA, VA 22314			MITCHELL, TEENA KAY	
		ART UNIT	PAPER NUMBER	
		3771		
		MAIL DATE	DELIVERY MODE	
		06/14/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/830,034	WOOD, THOMAS J.
	<b>Examiner</b>	<b>Art Unit</b>
	Teena Mitchell	3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 April 2004.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-33 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-33 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 23 April 2004 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/9/04; 5/17/05; 9130165</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Priority*

This application discloses and claims only subject matter disclosed in prior Application No. 11/008,669, filed 12/10/04, and names an inventor or inventors named in the prior application. Accordingly, this application may constitute a continuation or division. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

### *Drawings*

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the skirt, means for adjusting an aperture of the exhaust port, and an adjustable dial must be shown or the feature(s) canceled from the claim(s), the removable nasal insert. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

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consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

The disclosure is objected to because of the following informalities: The first paragraph of the specification needs to list the proper application for which priority is being claimed and the current status of any applications in which priority is being claimed. Correction is required.

### ***Claim Objections***

Claim 6 is objected to because of the following informalities: "...headgear flange is connected a flanged on the outer wall..." should be amended. Correction is required.

Claim 33 is objected to because of the following informalities: in line 6, "...the y-connector..." lacks antecedent basis. Line 12, "...outflowouflow..." needs to be corrected. Correction is required.

### ***Claim Rejections - 35 USC § 102***

**The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

**A person shall be entitled to a patent unless –**

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

**The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).**

**Claims 1, 4-6, 8-11, 13, 15, 18-20, 22-25, 27, and 29-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Strickland et.al. (6,679,265).**

Strickland in a nasal ventilation interface (10) discloses a cannula (see illustration of Fig. 2 below) connectable to a source of ventilation gas via two ventilation connectors (see illustration of Fig. 2 below); at least one reservoir flange (see illustration of Fig. 2 below) and in close proximity with at least one nasal insert (12, 13); at least one seal portion (26) positioned on a distal end of the at least one nasal insert; a central reservoir (see illustration of Fig. 2 below) between the at least one reservoir flange and the nasal insert; at least one exhaust flange (see illustration of Fig. 2 below) coupled to the central reservoir; and an exhaust port coupled to the exhaust flange positioned at a midpoint between the at least two ventilation connectors (see illustration of Fig. 2 below).

With respect to claim 4, Strickland discloses wherein an interior wall of the exhaust port maintains a substantially constant diameter (Figs. 2-7).

With respect to claim 5, Strickland discloses at least one headgear flange (see illustration of Fig. 1 below).

With respect to claim 6, Strickland discloses wherein the at least one headgear flange is connected on the outer wall of the cannula (Figs. 1, 2).

With respect to claims 8 and 22, Strickland discloses wherein at least one of the reservoir flange, nasal insert, and central reservoir are configured to provide laminar flow (Figs. 2-7).

With respect to claims 9 and 23, Strickland discloses wherein the exhaust port has a substantially oval cross section (Figs. 2-7).

With respect to claims 10 and 24, Strickland discloses wherein the seal portion (26) has a substantially oval cross section (Figs. 2-7).

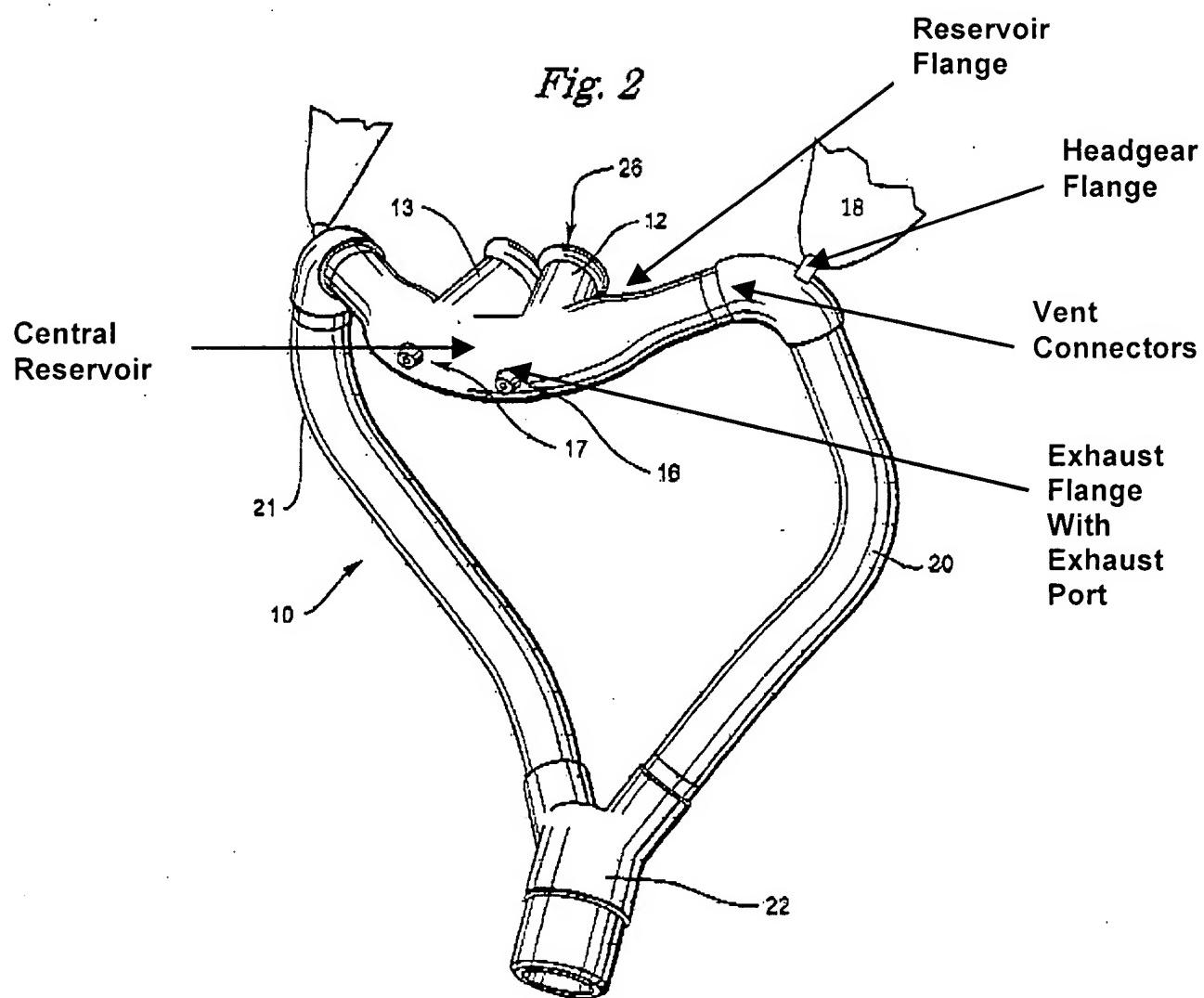
With respect to claims 11 and 25, the seal portion of Strickland is fully capable of receiving a skirt to prevent leakage (Figs. 2-7).

With respect to claim 29, Strickland discloses wherein the at least one nasal insert are removable (because the nasal insert of Strickland can be taken out of a user's nares it is readable upon the claimed limitations; Figs. 2-7).

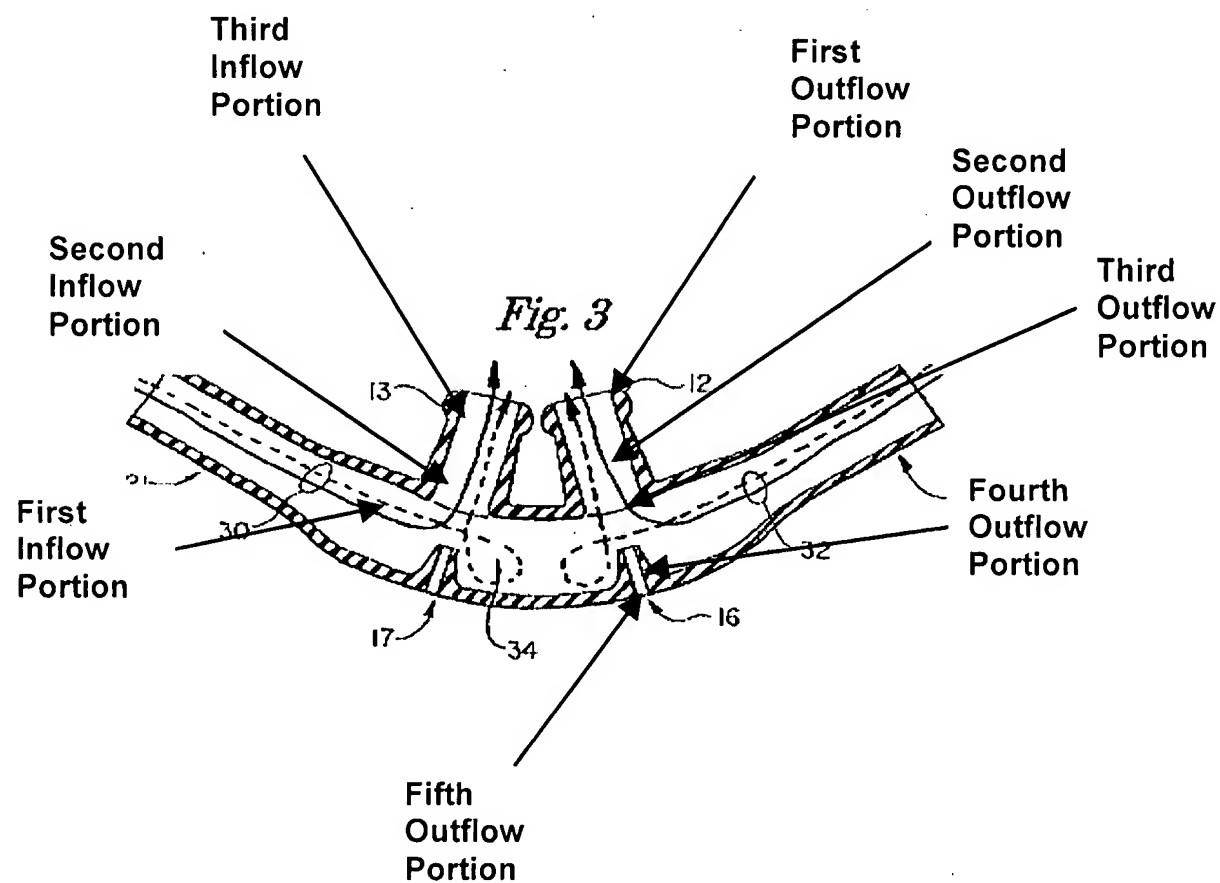
With respect to claim 30, Strickland discloses wherein the at least one nasal insert and seal portion create a seal with at least one naris (Figs. 2-7).

With respect to claim 31, Strickland discloses wherein the at least one nasal insert and seal portion create a seal in at least one naris with a slight expansion of the seal portion by a positive airway pressure (Col. 2, lines 55-67; inasmuch as the flange (i.e., nasal insert) is quite soft and conforms to the patient's nare's when positive

pressure is applied it would be inherent that the seal portion will create a seal with slight expansion.



With respect to claims 13, 15, 27, and 33, note rejection of claim 1 above (illustration of Fig. 3 below) for the claim inflow portions and outflow portions.



With respect to claim 18, Strickland discloses wherein the exhaust port has a substantially oval cross section (Figs. 2-7).

With respect to claim 19, Strickland discloses at least one headgear flange (See illustration of Fig. 2 above).

With respect to claim 20, Strickland discloses wherein the at least one headgear flange is connected to the reservoir outer wall (Fig. 2).

With respect to claim 32, Strickland discloses wherein the at least one nasal insert and seal portion are held in at least one naris by a headgear (Figs. 2-7).

***Claim Rejections - 35 USC § 103***

**The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:**

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 2, 12, 16, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strickland et.al. (6,679,265) in view of Russell (3,097,642).**

The difference between Strickland and claim 2 is an adjustable dial to adjust the aperture of the exhaust port. Russell in a ventilation interface teaches a dial (40, 44) providing a means to produce variable pressures within the lungs (Col. 4, lines 57-70) It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the exhaust port of Strickland to employ any well known adjustable dial doing so would have provided a means to produce variable pressures within the lungs including the dial taught by Russell.

With respect to claims 12, 16, and 26, note rejection of claim 2 above.

**Claims 7, 14, 21, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strickland et.al. (6,679,265).**

Regarding claims 7 and 21 Strickland discloses the claimed invention except for the headgear flange substantially U-shaped. It would have been an obvious matter of design consideration for one of ordinary skill in the art at the time the invention was made to have the headgear flange substantially U-shaped because Applicant has not disclosed that having the headgear flange substantially U-shaped provides an advantage, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the headgear flange of other shapes because the ability to hold the interface on a user is not affected by the shape of the headgear flange. Therefore, it would have been an obvious matter of design consideration to modify Strickland to obtain the invention as specified in claims 7 and 21.

Regarding claims 14 and 28, Strickland's shape of the flow portions provides for the claimed limitations of slowing the inflowing air velocity without a drop in pressure by allowing additional air molecules to enter the central reservoir, especially inasmuch as applicant has not shown any structural differences in the invention as that of Strickland.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

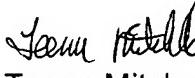
Claims 1-6, 8-10, 12, 13, 16-20, 22-27, and 32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 and 18-20 respectively of U.S. Patent No. 7,234,465. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the instant application can be found in claim 1 of patent '465. The patented claim is more specific and therefore "anticipates" instant application claim 1. *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993). Claim 2 of the instant application limitations can be found in claim 2 of patent '465. Claim 3 of the instant application limitations can be found in claim 1 of patent '465. Claim 4 of the instant application limitations can be found in claim 4 of patent '465. Claim 5 of the instant application limitations can be

found in claim 5 of patent '465. Claim 6 of the instant application can be found in claim 6 of patent '465. Claim 8 of the instant application limitations can be found in claim 7 of patent '465. Claim 9 of the instant application limitations can be found in claim 8 of patent '465. Claim 10 of the instant application limitations can be found in claim 9 of patent '465. Claim 12 of the instant application limitations can be found in claim 11 of patent '465. Claim 13 of the instant application can be found in claim 12 of patent '465. Claim 15 of the instant application limitations can be found in claim 12 of patent '465. Claim 16 of the instant application limitations can be found in claim 13 of patent '465. Claim 17 of the instant application limitations can be found in claim 1 of patent '465. Claim 18 of the instant application limitations can be found in claim 15 of patent '465. Claim 19 of the instant application limitations can be found in claim 16 of patent '465. Claim 20 of the instant application limitations can be found in claim 17 of patent '465. Claim 22 of the instant application limitations can be found in claim 18 of patent '465. Claim 23 of the instant application limitations can be found in claim 19 of patent '465. Claim 24 of the instant application limitations can be found in claim 20 of patent '465. Claim 32 of the instant application limitations can be found in claim 12 of patent '465.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Teena Mitchell  
Primary Examiner  
Art Unit 3771  
June 10, 2007

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